

Analysis Date: 18-06-2024

Re-test Date: 18-06-2027

MYCOPHENOLATE MOFETIL EP IMPURITY A

Identification

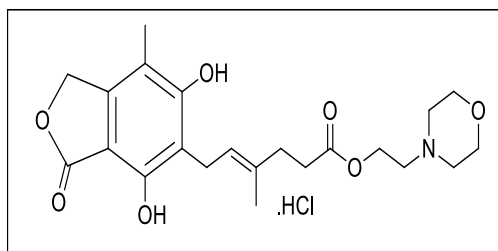
Chemical Name : 2-Morpholinoethyl-(E)-6-(1,3-dihydro-4,6-dihydroxy-7-methyl-3-oxo-5-isobenzofuranyl)-4-methyl-4-hexenoate hydrochloride

CAT No : ALL- MYC-2539

CAS No : 1322681-36-6

Molecular Formula : C₂₂H₂₉NO₇

Molecular Weight : 419.47



Analytical Information

Batch Code	: ALL- MYC-2539	HPLC Purity	: 95.45%
Solubility	: USP Diluent / EP Diluent (MEOH)	Potency	: 92.83 %
Appearance of Product	: Off White Solid	Mass	: Confirm
Long Term Storage	: -20°C	IR Analysis	: Confirm
Weight Content By TGA	: 1.750 %	¹H NMR	: Confirm
Residue Of Ignition	: 0.987 %		

Additional Information

%Potency = [100 - (Weight Content By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =
 [100 - (1.750 + 0.987) × 95.45]/100 = 92.83 %

Recommendation : Released

	Department	Name	Signature
Prepared and Reviewed by	Analytical	Mr.Vipul khadase Jr. Executive	
Approved By	QA&QC	Dr. Ashish Kechhe Director QA&QC	

Attachment : HPLC, Mass, ¹H NMR, IR, TGA

Shipping Condition : All Product are stable to be shipped at room temperature, unless otherwise specified

Corporate Office

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